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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/814,354 | 03/31/2004 | Rajesh V. Mehta | 86430AJA | 7757 |

7590 08/08/2006

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| EXAMINER |
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DRODGE, JOSEPH W

| ART UNIT | PAPER NUMBER |
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1723

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/814,354

Applicant(s)

MEHTA ET AL.

Examiner

Joseph W. Drodge

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>0406</u> . | 6) <input type="checkbox"/> Other: ____ |

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 9-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,4,5-9 and 11-13 of copending Application No. 10/814,354. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of '354 is genus to a combination of claims 1,4 & 9 of '026, differing only in omitting the step of depositing the formed particles, however, the formed particles of '354 are necessarily eventually deposited at some point of use. Claims 9-18 of '354 are analogous to, or obvious variants of claims 4-8,11 and 13 of '026.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1,3 and 5-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saim et al patent 6,858,166 in view of Gurth patent 6,132,080.

Saim et al disclose formation of micro or nano-particles by a process of admitting a supercritical fluid to a vessel, in which temperature and pressure are controlled (column 14, lines 21-45), agitating such vessel with a rotary agitator comprising an

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impeller of un-specified, given diameter relative to vessel diameter (column 14, line 63-column 15, line 6), introducing a 1st feed stream comprising a solvent and desired, active substance through a 1st introduction port and introducing a 2nd feed stream comprising the supercritical fluid through introduction ports both approximately within the vertical alignment of the diameter of the impeller (see especially figures 1 and 2 and column 18, lines 30-63). Particles are then precipitated within such vessel over a carrier bed. A major use of the Saim process is to produce a wide variety of pharmaceutical particles (column 6, lines 42-53).

The claims differ in requiring an explicit teaching of the impeller being of relatively small dimension relative to the dimension of the vessel, such that there is an annular distance exceeding at least one impeller diameter between edge of the impeller and inner wall of the vessel constituting a "bulk mixing zone". However, Gurth teaches a mixing vessel for the preparation of pharmaceutical products, or other delicate or sensitive materials (column 1, lines 23-30), in which the diameter of mixing impellers may vary relative to the mixing vessel diameter, and particularly in the figure 7 embodiment may be of quite small diameter relative to vessel diameter (column 3, lines 39-53 and column 5, line 65-column 6, line 18). It would have been obvious to one of ordinary skill in the art to have performed the process of Saim using a similar type and diameter of impeller to that of Gurth, so as to create an inward and subsequent outward relatively gentle flow of substances being mixed, so as to effect a more thorough, homogenous mixing, without creating turbulence or other mixing mechanisms that would damage the pharmaceutical substances being mixed.

Regarding dependent claims, Saim also discloses the following: for claims 3,7 and 6, flow of particles exhausted to an expansion or collection chamber that may constitute a distributor (column 21, lines 10-17), use of capillaries for claim 5 (column 13, line 15), for claim 8 forming of a dispersion (column 6, line 34), for claims 9-14 forming of nanosize particles of relatively uniform particle size (column 17, lines 5-8 and column 7, lines 6-8) , and for claims 15-18 forming of a wide range of pharmaceutical and industrial particles including the instantly claimed species (column 16, lines 33-45).

Claims 2 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saim in view of Gurth as applied to claims 1 and 3 above, and further in view of Sievers et al patent 5,639,441. Claims 2 and 4 further differ from Saim in requiring a continuous balanced flow through the mixing vessel and use of a back-pressure regulator for the vessel, respectively . Sievers teach such continuous flow through a vessel for utilizing supercritical fluid in the manufacture of micro-sized or smaller particles in column 7, lines 10-14 (also see Gurth at column 4, lines 45-47) and of backpressure regulators at column 19, line 66-column 20, line 1. It would have been further obvious to one of ordinary skill in the art to have adapted the Saim process to a balanced continuous flow mechanism, as in Sievers, in order to manufacture a much greater, industrial quantity of particles, and to have adapted the Sievers back-pressure regulator, in order to effect greater control of uniformity of particle size and processing pressures in the mixing vessel.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Drodge at telephone number

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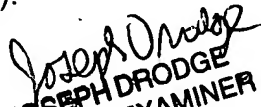
571-272-1140. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached at 571-272-1151. The fax phone number for the examining group where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either private PAIR or Public PAIR, and through Private PAIR only for unpublished applications. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JWD

August 4, 2006


JOSEPH DRODGE
PRIMARY EXAMINER